

Appl. No. 09/867,235  
Atty. Docket No. 8369  
Amdt. dated Sept. 20, 2004  
Reply to Office Action of April 21, 2004  
Customer No. 27752

### **REMARKS**

#### **Amendment**

Claims 27-31 are pending in the present application. No additional claims fee is believed to be due.

Claims 27-31 have been amended above. Support for these amendments can be found on page 6, line 5 through line 11 and on page 2, line 25.

Claim 29 has been amended to correct a typographical mistake regarding the term "topical". Support for this amendment is found at page 2, line 28 of the specification.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

#### **REJECTION UNDER 35 USC 102(b) OVER ROUQUET ET AL. (EP 908175)**

#### **I. Allowance of the claims as amended is proper in light of Applicants' showing of unexpected enhancement of delivery of oil-soluble actives.**

The Office Action maintains rejection of claims 27-31 under 35 USC §102(b) as being anticipated by Rouquet et al (EP '175). Applicants respectfully traverse this rejection.

The Office Action asserts that the Applicants have not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as the instantly claimed method of applying a composition comprising an oil-soluble skin care active, silicone oil, and silicone elastomer to the skin.

Applicants have demonstrated unexpected results showing that the present composition containing silicone elastomers does indeed enhance delivery of oil-soluble actives. Submitted herewith is a Declaration under 37 CFR §1.132. This Declaration speaks for itself.

The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. *In re Albert M.A. Rijckaert*, 9 F.3d 1531, 1534. According to MPEP 2112.01: "The prima facie case [that the products of the applicant and the prior art are the same] can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d 1252, 1255.

Appl. No. 09/867,235  
Atty. Docket No. 8569  
Amdt. dated Sept. 20, 2004  
Reply to Office Action of April 21, 2004  
Customer No. 27752

Rouquet provides no guidance to lead one of skill in the art to believe that silicone elastomers provide enhanced delivery of oil soluble actives (see also discussion below). In his discussion of vitamin actives, for example, Rouquet lists vitamin C (a water-soluble vitamin), together with vitamin A and palmitate (oil soluble vitamins), without providing any distinction or indication that would lead one of skill in the art to prefer one over the other. On the contrary, this list specifically leads one to believe that any or all are equally acceptable and effective. (Rouquet, p. 8 at [0033]).

Applicants' data however, via the 37 CFR §1.132 Declaration by Larry R. Robinson, clearly show enhanced delivery of an oil-soluble active to be utilized in the formula containing silicone elastomers. In Experiment 1, farnesol, an oil-soluble active, shows significantly greater penetration when compared to niacinamide, a water soluble active, in Experiment 2. Viewing the experiments individually, the data clearly show that when elastomers are present, penetration of oil-soluble actives is greatly enhanced as compared to when elastomers are absent. Applicants submit that this evidence of enhanced delivery of oil-soluble actives clearly shows an unexpected benefit not taught by Rouquet.

**II. Applicants' showing of unexpected results, together with the current amendments, addresses Examiner's remaining objections.**

The Office Action asserts on p. 4 that the open-ended transitional term "comprising" fails to exclude spherical particles, as claimed in Rouquet. Applicants respectfully point out that this transitional term has been amended, and that the claims have been amended to oil-soluble actives. The narrowed scope of this invention, together with the showing of unexpected enhanced delivery of oil-soluble actives, renders the claimed composition novel and unobvious. Applicants assert that these amendments, together with the showing of unexpected results, sufficiently address the Office Action's concerns.

The Office Action further rejects Applicants' argument that Rouquet provides no guidance which would lead one of skill in the art to choose oil-soluble actives, and refers to Rouquet's exemplification of the use of the oil-soluble active octyl methoxycinnamate (Parsol MCX™). Applicants respectfully point out that octyl methoxycinnamate is a sunscreen active (see Specification, p. 28, line 5; see also Rouquet, p. 8 at [0033]). Sunscreens are designed to only be effective when present on the skin's surface. In contrast, the present method is directed toward delivery of skin care actives *into* the skin, where they would have no sunscreen impact. Because sunscreens would be ineffective if not present on the skin's surface, use of octyl

Appl. No. 09/867,235  
Atty. Docket No. 8569  
Amdt. dated Sept. 20, 2004  
Reply to Office Action of April 21, 2004  
Customer No. 27752

methoxycinnamate cannot serve as guidance to one of skill in the art to choose an oil-soluble actives for penetration into the skin.

Applicants respectfully submit that these amendments, together with Applicants' showing of unexpected results, sufficiently addresses Examiner's concerns, and places the present claims in condition for allowance.

#### Summary

Applicants respectfully contend that the attached 37 CFR §1.132 Declaration by Larry R. Robinson is sufficient to establish unexpected results. The data clearly show enhanced delivery of oil-based actives when such actives are applied to the skin as part of a composition comprising silicone oil and silicon elastomers. Applicants respectfully assert that these unexpected results, together with the present amendments, are sufficient to overcome the rejections based on 35 USC § 102(b).

#### CONCLUSION

In light of the above remarks, and of the attached 37 CFR §1.132 Declaration by Larry R. Robinson, it is requested that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 102(b). Early and favorable action in the case is respectfully requested.

Applicants have made an earnest effort to place their application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, Applicants respectfully request reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 27-31

Respectfully submitted,

L.R. Robinson, *et al.*

By 

John M. Howell  
Attorney for Applicants  
Registration No. 33,713  
(513) 626-3792

September 20, 2004  
Customer No. 27752  
(Amendment-Response to Office Action.doc)  
Revised 6/2/2004